EFFECTIVENESS OF SELF-APPLIED TOURNIQUETS IN HUMAN VOLUNTEERS

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ABSTRACT

Background. Tourniquets are not commonly used in routine extremity trauma, but can be vital for hemorrhage control in austere conditions. **Objective.** To determine the effectiveness in human volunteers of currently available self-applied tourniquets for extremity hemorrhage. **Methods.** Seven tourniquets were tested on the thigh for elimination of detectable distal pulse by Doppler auscultation at the popliteal artery (experiment I, $n = 18$ subjects). The tourniquets that were effective in $\geq 80\%$ of subjects in experiment I were tested for effectiveness on the upper arm by auscultation at the radial artery (experiment II, $n = 12$ subjects). **Results.** Three of the seven tourniquets were effective in all subjects in experiment I; a fourth tourniquet was effective in 88%. Three of the four successful devices were also 100% effective in experiment II; the fourth was effective in 75%. Failure of tourniquets to eliminate distal Doppler pulse signal was due to inadequate mechanical advantage for tightening, device failure (breakage), or intolerable pinching or circumferential pain prior to pulse elimination. The Combat Application Tourniquet (North American Rescue Products, Inc.), the Emergency & Military Tourniquet (Delfi Medical Innovations, Inc.), and the Special Operations Forces Tactical Tourniquet (Tactical Medical Solutions, LLC) were all found to be 100% effective in elimination of distal arterial pulse in both the arm and the leg in all subjects. **Conclusion.** Some commercially available tourniquets do not reliably occlude arterial blood flow and may not be successful in preventing extremity exsanguination in a trauma patient. Potential purchasers of such devices should bear this in mind when selecting a device for clinical use. **Key words:** tourniquet; hemorrhage control; extremity trauma; exsanguination; vascular trauma.

Vascular injury to the extremities is extremely common in combat injury and is not uncommon in civilian blunt and penetrating trauma.[1-5] The volume of hemorrhage from such wounds can be life-threatening, and extremity exsanguination represents one of the most common causes of preventable death on the battlefield.[6] In civilian trauma, especially in rural and austere settings, uncontrolled severe extremity hemorrhage, though infrequent, can also be fatal.[2]

Tourniquets can be effective means to stop hemorrhage from severe extremity vascular injuries but, because of concerns about complications from their use, the devices have not been widely used for routine prehospital civilian trauma care.[7] Due to rapid patient transport times and the ready availability of definitive surgical hemorrhage control, the aversion to tourniquet use does not result in frequent civilian extremity exsanguination. The U.S. Armed Forces, operating in frequently austere conditions far from definitive care, have made the prevention of death from extremity hemorrhage a high priority. The use of tourniquets for severe extremity injuries that occur in remote locations and austere conditions is not limited to the battlefield, however. There are a number of potential civilian applications for the use of prehospital tourniquets, such as in wilderness environments, rural machinery accidents, and mass-casualty situations.

The military has an active interest in reducing combat deaths, especially those that might have been prevented with an effective tourniquet. To this end, military medical leaders have liberalized the doctrine for tourniquet use during combat operations.[8] In addition to the new doctrine regarding tourniquet use, the military

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medical community recognized the need for an improved tourniquet device that was more effective and easier to use than previous options and could be carried by all soldiers into combat.

With the onset of Operations Enduring Freedom (Afghanistan) and Iraqi Freedom, deploying combat units began purchasing commercially available tourniquet devices. These devices' efficacy had not been established because strap tourniquets are not subject to Food and Drug Administration testing and approval. In 2003, the U.S. Army Institute of Surgical Research (USAISR) was charged with evaluating commercially available tourniquet devices for efficacy in blood flow limitation in a controlled setting. This paper reports the results of this testing.

METHODS

Setting and Design

Study protocols and consent procedures were approved by the Brooke Army Medical Center Institutional Review Board and performed at the USAISR laboratory facility at Fort Sam Houston, Texas. The institute was established in 1943 and currently employs more than 250 military and civilian personnel to provide advanced care for thermal injuries and perform requirements-driven research in the field of combat casualty care. This research frequently involves the testing of commercial products and devices for use in combat casualty care applications.

The experimental study was prospective and had an observational, randomized, crossover design. Two experiments were performed in separate sessions; the first testing tourniquets were placed at the level of the proximal femur (experiment I) and the second at the level of the proximal humerus (experiment II). All tourniquets were tested in a single session with each subject in both experiments. Each device was assigned a number, and a random-number generator produced the order of testing of devices for each subject.

Tourniquet Selection

The USAISR solicited existing entities in private industry to provide tourniquets for testing via the publication of a request for information paper that was posted on a public website, www.fedbizopps.gov. Criteria had been previously established by a military trauma consensus panel regarding the required design and functional characteristics for candidate devices. These characteristics included weight not more than 230 grams, minimum strap width of 1 inch, easy application in less than 1 minute, easy release and reapplication, and no external power requirement. Other characteristics that were desirable but not required included width not less than 2 inches, one-handed, self-application to the upper extremity, capability of application to trapped limbs, protection from overtightening, and predicted cost for large-scale production not exceeding $25 per unit.

Nine companies responded to the Request for Information, each submitting ten sample devices for testing. The devices, their manufacturers, and specifications are presented in Table 1. Of the nine devices submitted, two did not meet the required design and functional requirements and were not tested. Photographs of the seven tested devices are shown in Figure 1.

Subjects and Measurements

Twenty healthy, normotensive men and women ranging in age from 23 to 47 years were enrolled in the study. The subjects were military and civilian employees of the USAISR. Eighteen subjects participated in experiment I

TABLE 1. Physical Characteristics of the Candidate Tourniquets

Tourniquet*	Weight (g)	Packaged L × W × H (cm)	Strap Width (cm)	Mechanical Augmentation[†]
CAT	59	266	3.8	Windlass (tensions strap within an outer sleeve)
SATS	136	448	3.8	Cam (tightens via cantilever system)
MAT	145	912	3.8	Block and tackle (multiple pulleys within a rigid outer frame)
SOFTT	160	746	3.7	Windlass (directly tensions strap)
H-Dyne	174	692	2.8	Elastic (four parallel elastic "bungee" cords)
LRT	183	410	5.1	Ratchet (similar to cargo strap)
EMT	215	491	9.1	Pneumatic (similar to blood pressure cuff)
LBT	260[‡]	401	2.4[§]	Ratchet (similar to cargo strap)
K²	990[‡]	4,597	3.8	Clamp (modified wood clamp)

CAT = Combat Application Tourniquet (North American Rescue Products, Inc.); SATS = Self-Applied Tourniquet System (Marketing Tactics, LLC); MAT = Mechanical Advantage Tourniquet (Bio Cybernetics International); SOFTT = Special Operations Forces Tactical Tourniquet (Tactical Medical Solutions, LLC); H-Dyne = One-Handed Tourniquet (Hemodyne, Inc.); LRT = Last Resort Tourniquet (Hammerhead, LLC); EMT = Emergency & Military Tourniquet (Delfi Medical Innovations, Inc.); LBT = London Bridge Tourniquet (London Bridge Trading Company, LTD); K² = K² Tactical Tourniquet (HGW).

[†] "Mechanical augmentation" refers to the method employed be each tourniquet to gain mechanical advantage in the tightening process.

[‡] >250 g (devices not tested).
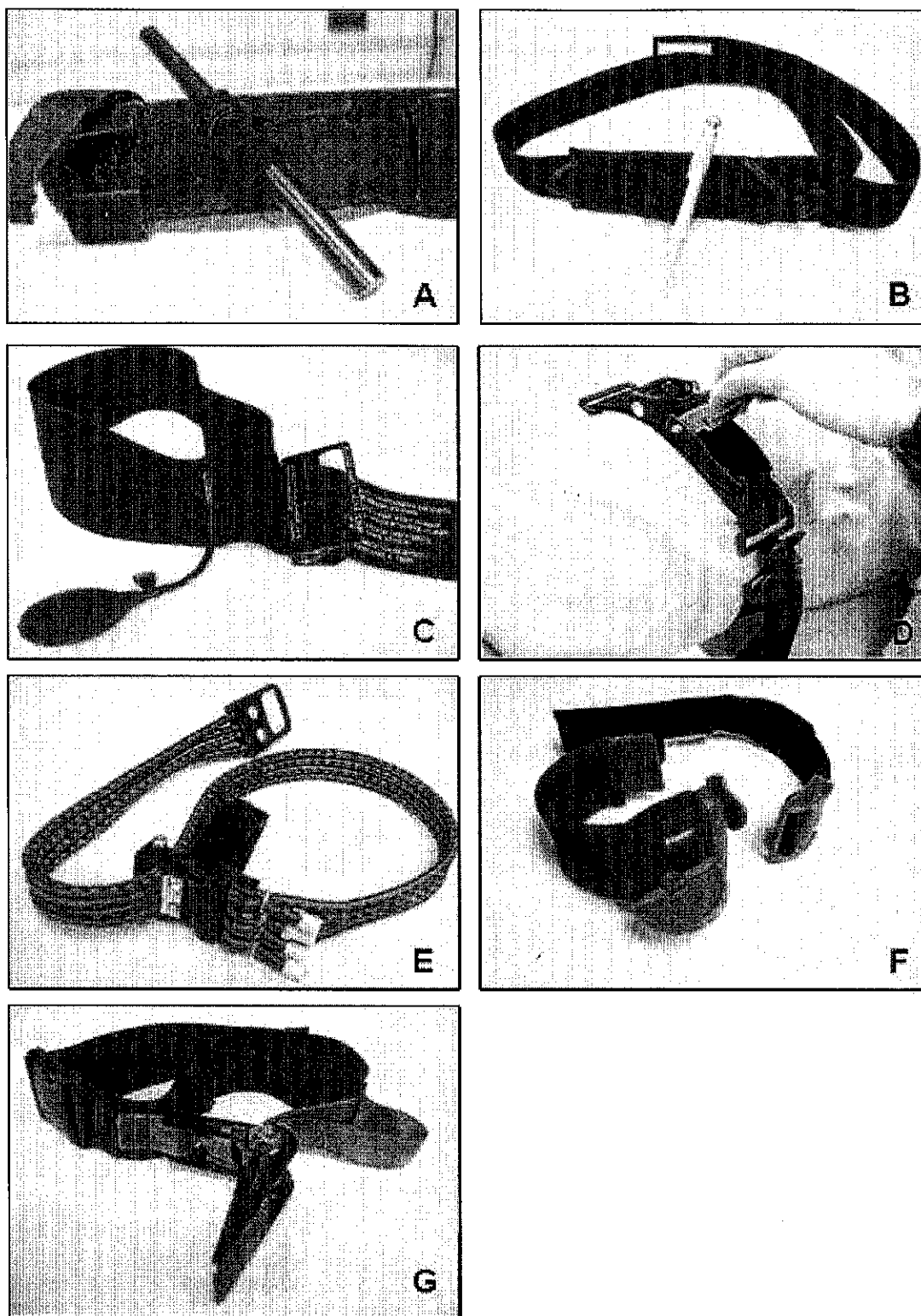
[§] <2.54 cm (device not tested).

FIGURE 1. A) The Combat Application Tourniquet (North American Rescue Products, Inc.). B) The Special Operations Forces Tactical Tourniquet (Tactical Medical Solutions LLC). C) The Emergency & Military Tourniquet (Delfi Medical Innovations, Inc.). D) The Self-Applied Tourniquet System (Tactical Medical Solutions, LLC). E) The One-Handed Tourniquet (Hemodyne, Inc.). F) The Mechanical Advantage Tourniquet (Bio Cybernetics International). G) The Last Resort Tourniquet (Hammerhead, LLC.).

(16 male, 2 female). Twelve subjects participated in experiment II (10 male, 2 female). Ten of the subjects in experiment II had also participated in experiment I. Both experiments were conducted with all subjects wearing surgical "scrubs" of identical fabric composition. Prior to testing, each subject's height, weight, and limb circumferences (experiment I, mid-thigh; experiment II, mid-upper arm) were measured, along with

TABLE 2. Baseline Characteristics of the Subjects*

	Experiment I—Leg (n = 18)		Experiment II—Arm (n = 12)	
	Mean ± SD	Range	Mean ± SD	Range
Age (yr)	35.3 ± 7.3	23–47	35.5 ± 7.9	22–47
Weight (kg)	83.4 ± 10.7	65–103	85.5 ± 13.9	65–103
Height (cm)	177 ± 7	163–188	178 ± 8	163–191
Limb circumference (cm)	59.5 ± 4.6	51.5–67.5	34.0 ± 4.2	28.5–42.5
Heart rate (beats/min)	65 ± 9	42–80	62 ± 7	50–72
Blood pressure (mm Hg)				
Systolic	122 ± 7	100–130	119 ± 6	110–128
Diastolic	75 ± 9	58–90	79 ± 4	70–88

*Subject data for male and female subjects are combined: experiment I: 2 female, 16 male; experiment II: 2 female, 10 male. The thigh circumferences of the two females fell into the 50th percentile for U.S. male soldiers. The overall range of thigh circumferences was 51.5–67.5 cm, corresponding to the 95th and 5th percentiles of U.S. male soldiers, respectively. Seven of the 18 circumferences were above the 80th percentile. (U.S. soldier anthropometric data from: Gordon CC, Churchill T, Clauser CE, et al. Anthropometric Survey of U.S. Army Personnel: Methods and Summary Statistics 1988. Technical Report. Natick, MA: U.S. Army Natick Research, Development, and Engineering Center, March 24, 1989. Report No.: Natick/TR-89/044.)

the subject's resting blood pressure and heart rate. Descriptive data are presented in Table 2.

The primary endpoint of both experiments was the elimination of Doppler signal by auscultation of the popliteal (experiment I) or radial (experiment II) artery (IMEXDOP CT+, Nicolet Vascular, Madison, WI). The Doppler provided investigators and subjects with continuous auditory feedback during the tightening of each tourniquet. Prior to testing each tourniquet, subjects were instructed on proper placement and use according to instructions provided by the manufacturer. During the experiments, subjects applied and tightened their own tourniquets and were instructed to continue tightening the tourniquet until either the audible Doppler signal ceased or the pain from the tourniquet became intolerable. If the subject successfully occluded blood flow, the tourniquet was slowly released to confirm reestablishment of Doppler signal and ensure that loss of signal was due to the tourniquet and not movement of the ultrasound probe.

In some instances, tourniquets broke or malfunctioned during a test. In these cases, the event was documented and the test was repeated with a new, identical tourniquet. In cases where the subject could not occlude flow secondary to intolerable pain, the subject was asked whether the pain was diffuse and circumferential or primarily pinching from one or more of the tourniquet components.

Experimental Procedures

In experiment I, with the subject seated and the leg extended, the site of maximal popliteal Doppler signal at the level of the knee was located and marked. The subject positioned the tourniquet around his or her prox-

imal thigh and secured it in place using both hands. The experimenter then reestablished a Doppler signal and the subject tightened the tourniquet. Subjects alternated between right and left legs, with 5 minutes between tests. The initial leg was alternated between sessions, e.g., subject 1 applied the first tourniquet to the right leg, subject 2 to the left.

Through consultation with military medical experts, the U.S. Armed Forces have established a minimal effectiveness standard for tourniquets. To be considered effective, devices must occlude distal arterial flow when applied to the thigh in at least 80% of patients. In this study, tourniquets were required to occlude arterial flow in 15 of the 18 (83%) subjects to meet this standard and proceed to testing on the arm.

In experiment II, with the subject seated and the non-dominant arm extended, the site of maximal radial arterial signal at the level of the wrist was located by Doppler auscultation and marked. Following instruction as above, the subject applied the tourniquet using his or her dominant hand. All other procedures were the same as those outlined in experiment I.

Data Analysis

Descriptive statistics were used for baseline patient data. Tourniquets were judged effective if they were successful in occluding arterial flow in ≥80% of subjects.

RESULTS

Experiment I

The Combat Application Tourniquet (CAT; North American Rescue Products, Inc., Simpsonville, SC), the Emergency & Military Tourniquet (EMT; Delfi Medical Innovations, Inc., Vancouver, BC, Canada), and the Special Operations Forces Tactical Tourniquet (SOFTT; Tactical Medical Solutions, LLC, Raeford, NC) were effective in eliminating distal blood flow in the leg of all subjects (Table 3). The Mechanical Advantage Tourniquet (MAT; Bio Cybernetics International, La Verne, CA) was effective in 88% (14/16) of the subjects tested. The MAT was not retested following a mechanical failure in two cases. The remaining three tourniquets all fell below the 80% success rate. Causes of failure included intolerable circumferential or pinching pain prior to occlusion of flow, failure of the tourniquet to maintain tension (slipping), and inability of the subject to generate the requisite tension to occlude flow (physical limitation).

A total of seven mechanical failures occurred in two devices: four MAT and three Last Resort Tourniquets (LRT; Hammerhead, LLC, Princeton, NJ). In these cases, the trial was repeated with a replacement tourniquet,

TABLE 3. Results of Experiment I*

	CAT	SOFTT	EMT	MAT	LRT	SATS	H-Dyne
Percent effective	100	100	100	88	67	44	22
Number effective	18/18	18/18	18/18	14/16†	12/18	8/18	4/18
Failures (number of devices)							
Circumferential pain	n/a	n/a	n/a	1	2	2	4
Pinch pain	n/a	n/a	n/a	1	1	0	0
Slipping	n/a	n/a	n/a	0	3	0	5
Physical limitation	n/a	n/a	n/a	0	0	8	5

*See footnote of Table 1 for explanations of tourniquet abbreviations.
†N = 16 due to failure to replace and retest two devices following mechanical failures.

and breakage is not reflected in the effectiveness data.

Experiment II

The CAT, SOFTT, and EMT were effective in all subjects tested (Table 4). The MAT was effective in 75% (9/12). The failure of the MAT was due in all cases to intolerable pinching pain.

DISCUSSION

Tourniquet Use

Tourniquet use in extremity trauma is familiar to military field medical personnel, and the tourniquet is frequently a lifesaver in combat medicine around the world.[9] The controversy regarding the use of tourniquets is, however, a subject of active debate.[10] Despite their known benefit and relative lack of complications from use in military situations, the devices are seen as a last resort for control of hemorrhage in civilian prehospital care.[7,9] Though exsanguinating extremity hemorrhage is uncommon in civilian practice, tourniquets can still play a role in the prehospital care of severely injured patients who fail other methods of hemorrhage control, especially in remote or austere environments where transport times to definitive surgical hemorrhage control are prolonged.

Extremity injury is common in wilderness medicine, where injuries can occur to isolated individuals far from even basic emergency medical services.[11] An accessible, easy-to-apply, effective tourniquet can be lifesaving in these situations in the face of severe extremity hemorrhage. Rural and farm machinery accidents represent other potential applications for tourniquets in civilian prehospital care. These incidents frequently involve long transport times and mangled extremities with severe blood loss.[12,13] In mass-casualty situations, even in urban environments, tourniquets can provide effective hemorrhage control for severely injured extremities in triaged patients awaiting transport to definitive care. While tourniquets are unlikely to significantly impact mortality for patients who will reach definitive care quickly, some advantage may be gained by reducing blood loss through a more liberal use of prehospital tourniquets in civilian extremity hemorrhage. Rapid transport to definitive care and tourniquet removal in the civilian environment will minimize the potential for limb damage resulting from extended periods of tourniquet application.

Tourniquet Design

The identification of both appropriate doctrine for tourniquet use and effective and simple-to-use devices is vital to their successful use in extremity trauma in military or civilian applications. Elimination of distal arterial blood flow is the primary purpose of applying a tourniquet and any device that fails to occlude distal arterial flow is unacceptable. A tourniquet tight enough to occlude venous but not arterial flow may exacerbate hemorrhage from damaged arteries and cause significant injury to underlying and distal tissues. An inadequate tourniquet may exacerbate bleeding from wounded soft tissues distal to the device by allowing continued arterial flow to these tissues while preventing of venous return to the circulation. Fewer than half of the commercially available tourniquets tested in this study effectively eliminated distal arterial blood flow in more than 80% of tested subjects. This has significant implications for the care of patients in that there is a potential for the use ineffective devices to control life-threatening hemorrhage.

In order for a tourniquet to be effective, it must employ some form of mechanical advantage to occlude blood flow. The use of mechanical advantage allows

TABLE 4. Results of Experiment II*

	CAT	SOFTT	EMT	MAT
Percent effective	100	100	100	75
Number effective	12/12	12/12	12/12	9/12†

*See footnote of Table 1 for explanations of tourniquet abbreviations.
†Failure in all cases was due to introlerable pinching pain.

the tourniquet strap to overcome the barrier of soft tissue and provide compression to the artery. This is especially important in the lower extremity because the pressure required to occlude blood flow increases exponentially with limb circumference.[14-16] All of the devices that we tested employed mechanical advantage; however, only those devices employing a windlass (CAT, SOFTT); a block-and-tackle system (MAT), or pneumatic compression (EMT) were able to occlude flow in the lower extremity of more than 80% of our subjects.

Another consideration in tourniquet design that has functional implications is the width of the strap. For pneumatic surgical tourniquets, it has been shown that a wider strap allows for occlusion of blood flow at a lower pressure, helping to minimize the potential for damage to underlying tissues, especially nerves. Animal studies have demonstrated a direct relationship between nerve injury and tourniquet pressure.[17,18] The extent of circumferential pain induced by a given device is likely related to the potential for compression injury to underlying nerves, and thus self-limitation with intolerable pain may act as an indirect screen for the tissue compression and tissue damage caused by the tourniquet. In our study, the EMT had the greatest strap width, suggesting that it may be safer to the underlying tissues than the other devices tested.

LIMITATIONS

It is important to note that we made no attempt to simulate field conditions in these experiments. Potential interactions with field clothing, challenging environmental conditions, and user education in tourniquet use remain to be evaluated. Human subject protection considerations made it impossible to determine whether the tested devices that failed to eliminate Doppler signal due to intolerable pain would be able to accomplish this whether pain were not considered. In this way, some potentially effective tourniquets may have been labeled as failures.

A limited number of companies responded to our request for participation, thus there are likely available tourniquets that were not included in our testing. Given our findings, it is conceivable that there are many currently available effective and ineffective tourniquets.

We had to modify one of the devices (One-Handed Torniquet, Hemodyne, Inc., Bethesda, MD) from the manufacturer's design and remove a serrated metal plate that was meant to secure the device to prevent slippage. With this plate in place, expeditious removal of the device was very difficult and the tourniquet was considered to be unsafe. Even if all slippage failures potentially due to the missing plate were counted as successes, the success rate in the lower extremity would

have been only 50%, and the device would not have progressed to testing in the arm.

CONCLUSIONS

Despite aversion to their use in civilian prehospital trauma care, tourniquets have the potential to be lifesaving interventions. Not all commercially available devices are equally efficacious, however. Three tourniquets were identified in this study that met established criteria for design and efficacy for use in the Armed Forces. The CAT, SOFTT, and EMT all effectively eliminated distal Doppler signal in the arms and legs of all subjects tested and are recommended for field use. The high rate of failure of commercially available devices to meet efficacy criteria in this study suggests that civilian and military entities considering acquisition of tourniquets for use as lifesaving interventions carefully examine the characteristics of candidate devices and test them in a systematic fashion prior to making a decision.

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